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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,232	04/26/2006	Christina Mertens	I-2003.019 US	4106

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
06/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,232	MERTENS ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 22-24 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Note that claim 22 depends from both claims 6 and 1.

Claims 1-20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "wherein, at a spinosyn dosage of less than equal to 30 mg/kg, the formulation is capable of achieving an efficacy of 90% in controlling flea and tick infestations in an animal 7 days after administration of the formulation as may be determined by a parasite assessment test" (claim 1), "wherein the one or more spinosyns are administered to the animal at a dosage of less than or equal to 30 mg/kg so as to achieve persistent efficacy of 90% in killing flea ticks for 7 days after the treatment" (claim 6), "on a weekly basis, subsequently administering to the animal a reduced dosage of the formulation of claim 1 so as to maintain 90% efficacy against ticks for up to 7 days after the subsequent administration" (claim 22) and "the reduced dosage comprises less than or equal to 15 mg/kg of one or more spinosyns" (claim 23) is not disclosed in the specification as originally filed.

Applicant's arguments filed February 27, 2009 have been fully considered but they are not persuasive.

Applicant contends that support for new claims 22-24 and the amendments to claims 1 and 6 may be found throughout the specification and at Example I, Table 3. This argument has not been found persuasive. Example 1 is limited to administration of compound 22c and spinosad wherein compound 22c was administered with the initial dose of 4mg/kg followed by 3 weekly additional doses of 2 mg/kg and spinosad was administered at an initial dose of 30 mg/kg, followed by weekly doses of 15 mg/kg. However, there is no disclosure that a combination of any compound encompassed by the formula (I) at any dosage in combination with ant spinosyn compound at a dosage of 30 mg/kg or less is capable of achieving efficacy of 90%. Further note that the terminology "less than or equal to 15 mg/kg" (claim 23) reads on a dosage of 1 mg/kg. There is no evidence of record that such a dosage would be effective.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the European Patent No. 0 412 849 A in combination with the International Patent No. WO 01/11963 A1.

The European Patent discloses compounds of formula (I) active against ecto-parasites (pages 2-3). The International Patent discloses spinosyns active against ecto-parasites (pages 2-3). It would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made to combine two known compounds active against ecto-parasites into a single composition because such a person would have expected the resulting composition to be active against ecto-parasites.

Applicant's arguments filed February 27, 2009 have been fully considered but they are not persuasive.

Applicant contends that the references do not teach or suggest that the compounds of formula I and spinosyns could be combined in the manner claimed. This argument has not been found persuasive. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose…[T]he idea of combining them flows logically from their having been individually taught in the prior art." Inre Kerkhoven 626 F. 2d 846, 820, 205 USPQ 1069, 1072 (CCPA).

Applicant also contends that the European Patent does not disclose controlling tick and flea infestations on an animal. This argument has not been found persuasive since the European Patent discloses that the compounds of formula (I) "are active systemically, especially against animal ecto- and endoparasites" (page 3, lines 34-35). Further note that the International Patent discloses the administration of spinosyns at a dosage of "from about 10 to about 50 mg/kg" (page 10, lines 17-20). Note that the reference's teaching is not limited to its preferred embodiment. Further, the test data presented in the specification, limited to two specific compounds at specific dosages is clearly not commensurate with the full scope of the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623